[Docket No. 88F-0199]

Dow Chemical Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the Dow Chemical Co. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of ethylene-octene copolymers, ethylene-octene-hexene copolymers, ethylene-octene-butene copolymers, ethylene-octene-propylene copolymers, and ethylene-octene-4-methylpentene-1 copolymers, which contain not less than 75 weight percent of polymer units derived from ethylene as articles or components of articles intended to contact food.

FOR FURTHER INFORMATION CONTACT: Vir Anand, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 8B4091) has been filed by the Dow Chemical Co., 1803 Bldg., Door 7, Midland, MI 48674, proposing that § 177.1520 *Olefin polymers* (21 CFR 177.1520) be amended to provide for the safe use of ethylene-octene copolymers, ethylene-octene-hexene copolymers, ethylene-octene-butene copolymers, ethylene-octene-propylene copolymers, and ethylene-octene-4-methylpentene-1 copolymers, which contain not less than 75 weight percent of polymer units derived from ethylene as articles or components of articles for use in contact with food.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: June 16, 1988.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 88-14269 Filed 6-23-88; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 88E-0183]

Determination of Regulatory Review Period for Purposes of Patent Extension; Naftin®

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Naftin® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESS: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: I. David Wolfson, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) generally provides that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under that act, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Naftin® (naftifine hydrochloride). Naftin® Cream is indicated for the topical treatment of tinea cruris and tinea corporis. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Naftin® (U.S. Patent No. 4,282,251) from Sandoz Pharmaceuticals Corp. and requested FDA's assistance in determining the patent's eligibility for patent term restoration. FDA, in a letter dated May 24, 1988, advised the Patent and Trademark Office that the human drug product had undergone a regulatory review period and that the active ingredient, naftifine hydrochloride, represented the first permitted marketing or use of that active ingredient. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Naftin® is 2,903 days. Of this time, 2,189 days occurred during the testing phase of the regulatory review period, while 714 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective:* March 21, 1980. The applicant claims January 17, 1980, as the effective date of the first investigational new drug application (IND) related to the approved product. However, FDA records indicate that the first IND became effective on March 21, 1980, when IND 17-148 was removed from clinical hold.

2. *The date the application was initially submitted with respect to the Human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act:* March 18, 1986. The applicant claims that the new drug application for the product (NDA 19-599) was initially submitted on March 14, 1986. However, FDA records indicate that NDA 19-599 was received on March 18, 1986.

3. *The date the application was approved:* February 29, 1988. FDA has verified the applicant's claim that NDA 19-599 was approved on February 29, 1988.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension,

this applicant seeks 730 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before August 23, 1988, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before December 21, 1988, for a determination regarding whether the applicant for extension acted with the due dilligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, Part 1, 98th Cong., 2d Sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 16, 1988.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 88-14267 Filed 6-23-88; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 88M-0162]

CIBA Vision Corp.; Premarket Approval of CIBA Vision™ Lens Drops

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Ciba Vision Corp., Atlanta, GA, for premarket approval, under the Medical Device Amendments of 1976, of the Ciba Vision™ Lens Drops for use to lubricate and rewet soft (hydrophilic) and hard contact lenses. After reviewing the recommendation of the Ophthalmic Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of March 31, 1988 of the approval of the application.

DATE: Petitions for administrative review by July 25, 1988.

ADDRESS: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: David M. Whipple, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7940.

SUPPLEMENTARY INFORMATION: On December 8, 1986, Ciba Vision Corp., Atlanta, GA 30348, submitted to CDRH an application for premarket approval of the Ciba Vision™ Lens Drops. The Ciba Vision™ Lens Drops are indicated for use to lubricate and rewet soft (hydrophilic) and hard contact lenses.

On February 27, 1987, the Ophthalmic Devices Panel, and FDA advisory committee, reviewed and recommended approval of the application. On March 31, 1988, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above), and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

A copy of all approved labeling is available for public inspection at CDRH—contact David M. Whipple (HFZ–460), address above.

The labeling of the Ciba Vision™ Lens Drops states that the solution is indicated for use to lubricate and rewet soft (hydrophilic) and hard contact lenses that have been approved for marketing are advised that whenever CDRH publishes a notice in the Federal Register of the approval of a new solution for use with an approved soft contact lens, the manufacturer of each lens or PMA holder shall correct its labeling to refer to the new solution at the next printing or at such other time as CDRH prescribes by letter to the applicant.

Opportunity for Administrative Review

Section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 360e(g)), for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under Part 12 (21 CFR Part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall sumbit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before July 25, 1988, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h), 90 Stat. 554–555, 571 (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: June 16, 1988.

John C. Villforth,

Director Center for Devices and Radiological Health.

[FR Doc. 88-14270 Filed 6-23-88; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 88M-0160]

Versaflex Delivery Systems, Inc.; Premarket Approval of the Versaflex ™ Buchbinder ™ Omniflex ™ PTCA Catheter System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Versaflex Delivery Systems, Inc., San Diego, CA, for premarket approval, under the Medical Device Amendments of 1976, of the Versaflex.™ Buchbinder.™ Omniflex ™ PTCA Catheter System for use in patients with coronary artery disease. After reviewing the recommendation of the Circulatory